

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

MDL NO. 13-02419-RWZ

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC.
PRODUCTS LIABILITY LITIGATION

THIS ORDER APPLIES TO ALL CASES AGAINST
THE SPECIALTY SURGERY DEFENDANTS¹

MEMORANDUM OF DECISION AND ORDER

April 24, 2017

ZOBEL, S.D.J.

Plaintiffs' Steering Committee ("PSC") moves for judgment on the pleadings regarding the Specialty Surgery Center ("SSC") Defendants' and Calisher and Associates' (collectively, "Defendants") affirmative defense of comparative fault to the extent they attribute fault to certain non-party governmental entities.² Docket # 3249.

I. Legal Standard

"[A] court may enter judgment on the pleadings only if the uncontested and properly considered facts conclusively establish the movant's entitlement to a favorable judgment." Aponte-Torres v. Univ. of Puerto Rico, 445 F.3d 50, 54 (1st Cir. 2006). A Rule 12(c) motion "implicates the pleadings as a whole," id. at 55, and thus, includes

¹ Specialty Surgery Center, PLLC; Kenneth R. Lister, M.D.; Kenneth R. Lister, M.D., P.C.

² The PSC's motion is limited to Defendants' affirmative comparative fault defense as to the Food and Drug Administration, the Massachusetts Board of Registration in Pharmacy, the Tennessee Board of Pharmacy, and the Tennessee Department of Health. See Docket # 3249, at 1.

consideration of both plaintiffs' complaint and defendants' answer. See NEPSK, Inc. v. Town of Houlton, 283 F.3d 1, 8 (1st Cir. 2002). Here, because the PSC moves for judgment on the pleadings regarding Defendants' affirmative defense, "the parties agree that the source of the pertinent facts is the [Defendants' answer]." Aponte-Torres, 445 F.3d at 55; see also Docket # 3250, at 6 ("[T]he Court need look no further than the facts as alleged in the Defendants' respective Answers to reach [the conclusion that Defendants' comparative fault defenses attributing fault to certain non-party governmental entities fails as a matter of law]."). For purposes of a motion for judgment on the pleadings, "the court must view the facts contained in the pleadings in the light most favorable to the nonmovant and draw all reasonable inferences therefrom to the nonmovant's behoof." R.G. Fin. Corp. v. Vergara-Nunez, 446 F.3d 178, 182 (1st Cir. 2006).

II. Discussion

The PSC argues that under Tennessee's public duty doctrine Defendants cannot establish a prima facie case of negligence against those non-party governmental entities, and as a result, they cannot establish comparative fault of the non-party governmental entities. In response, Defendants contend that Tennessee law allows for fault to be allocated to immune non-parties even if they are immune from liability under the public duty doctrine.

A. Comparative Fault Doctrine Under Tennessee Law

I begin by reviewing the law of comparative fault under Tennessee law. In McIntyre v. Balentine, the Tennessee Supreme Court "replace[d] the common law defense of contributory negligence with a system of comparative fault." 833 S.W.2d 52,

53 (Tenn. 1992). In adopting this modified system of comparative fault, the court explained that:

[F]airness and efficiency require that defendants called upon to answer allegations in negligence be permitted to allege, as an affirmative defense, that a nonparty caused or contributed to the injury or damage for which recovery is sought. In cases where such a defense is raised, the trial court shall instruct the jury to assign this nonparty the percentage of the total negligence for which he is responsible. However, in order for a plaintiff to recover a judgment against such additional person, the plaintiff must have made a timely amendment to his complaint and caused process to be served on such additional person.

Id. at 58. In Carroll v. Whitney, the Tennessee Supreme Court interpreted this language and explained that “[a] plaintiff’s ability to bring a cause of action was only important—to the extent that it mattered at all [to the McIntyre court’s analysis]—in determining whether the plaintiff could recover damages, not whether a jury could apportion fault to a nonparty.” 29 S.W.3d 14, 17 (Tenn. 2000). Accordingly, the court in Carroll held that in general, a defendant may assert comparative fault against a non-party who is immune from suit. Id. at 19 (holding that lower court did not err in allowing jury to apportion 100% fault to immune non-parties).

In order to assert this defense, however, Defendants are “required to prove a prima facie case of negligence against the nonparty [they] contend[] was negligent.” Free v. Carnesale, 110 F.3d 1227, 1231 (6th Cir. 1997). “To bring a successful negligence claim, [the party asserting the claim] must establish each of the following elements: (1) a duty of care owed by the [non-party] to the plaintiff; (2) conduct by the [non-party] falling below the applicable standard of care that amounts to a breach of that duty; (3) an injury or loss; (4) causation in fact; and (5) proximate, or legal, causation.” Staples v. CBL & Assocs., Inc., 15 S.W.3d 83, 89 (Tenn. 2000).

The central issue here is whether Defendants can meet the first element to assert a negligence claim against the governmental entities; namely, whether the governmental entities owed a duty of care to plaintiffs.

B. Public Duty Doctrine

The PSC alleges that Defendants cannot assert comparative fault against the non-party governmental entities because Tennessee's public duty doctrine eliminates the required element of a legal duty. "The public duty doctrine 'shields a public employee from suits for injuries that are caused by the public employee's breach of a duty owed to the public at large.'" Holt v. City of Fayetteville, No. M2014-02573-COA-R3-CV, 2016 WL 1045537, at *4 (Tenn. Ct. App. 2016) (quoting Ezell v. Cockrell, 902 S.W.2d 394, 397 (Tenn. 1995)). Under Defendants' interpretation of this doctrine, a duty still exists—albeit a general one owed to the public at large—and the governmental entities "can still breach [that] duty[.]" Docket # 3278, at 5. That interpretation, however, is incorrect.

Under Tennessee's public duty doctrine, "a duty owed to everyone is a duty owed to no one." Brown v. Hamilton County, 126 S.W.3d 43, 48 (Tenn. Ct. App. 2003). "The doctrine is not a form of immunity at all, but rather 'negates the duty element required to prove negligence, such that there can be no cause of action for injuries sustained as the result of an alleged breach of public duty to the community as a whole.'" Kern v. City of Gerald, No. 4:08CV713 CDP, 2008 WL 4831775, at *3 (E.D. Mo. Nov. 4, 2008) (quoting Southers v. City of Farmington, 263 S.W.3d 603, 612 (Mo. June 10, 2008)); cf. Biscan v. Brown, 160 S.W.3d 462, 475 (Tenn. 2005) (upholding trial court's instruction to jury that it was not allowed to apportion fault to a non-party

because defendants, as a matter of law, could not establish the element of causation). In Biscan, the court explained that although “fault may be apportioned to those who are immune or ‘effectively immune’ from liability [under Carroll]³,” a jury should not be permitted to apportion fault “to one who is statutorily without fault.” 160 S.W.3d at 475. Thus, there is a distinction between “restrict[ing] the remedy for a cause of action” and “remov[ing] that cause of action entirely, making a person or entity . . . immune from fault as well as immune from liability.” Id. at 474. The public duty doctrine does not merely make governmental entities immune from liability, as Defendants contend, rather, it makes them immune from fault because it eliminates a duty on the governmental entities in the first instance. Cf. Ezell, 902 S.W.2d at 397 (explaining that “the imposition of a duty in any negligence action reflects society’s contemporary policies and social requirements concerning the right of individuals and the general public to be protected from another’s act or conduct”).

C. Special Duty Exception

Nonetheless, “[s]tates adhering to the public duty doctrine, including Tennessee, have recognized an exception to the rule of no-liability that applies where a ‘special relationship’ exists between the plaintiff and the public employee, which gives rise to a ‘special duty’ that is more particular than the duty owed by the employee to the public at large.” Ezell, 902 S.W.2d at 401. A “special duty” of care exists in three

³ Notably, in Carroll, the immune non-parties were two state resident physicians who were immune from suit because of their status as state employees. See Tenn. Code § 9-8-307(h) (immunizing state employees from liability for acts or omissions within the scope of the employee’s employment). The Carroll court never discusses whether the resident physicians owed the plaintiff’s deceased child a duty of care, presumably because “[t]he existence of a physician’s duty arises out of the professional relationship between the physician and his or her patient.” Church v. Perales, 39 S.W.3d 149, 164 (Tenn. Ct. App. 2000).

circumstances. Specifically, “when 1) officials, by their actions, affirmatively undertake to protect the plaintiff, and the plaintiff relies upon the undertaking; 2) a statute specifically provides for a cause of action against an official or municipality for injuries resulting to a particular class of individuals, of which the plaintiff is a member, from failure to enforce certain laws; or 3) the [party asserting the action] alleges a cause of action involving intent, malice, or reckless misconduct.” Id. at 402. As a result, Defendants can succeed on their claim of comparative fault against the non-party governmental entities only if they can establish that the governmental entities owed a “special duty” to plaintiffs.

Here, Defendants assert that the special duty exception does apply to the Food and Drug Administration (“FDA”) and the Massachusetts Board of Registration in Pharmacy (“MBOP”) because their actions involved reckless misconduct. “Reckless conduct is defined as taking place ‘when a person is aware of, but consciously disregards, a substantial and unjustifiable risk of such a nature that its disregard constitutes a gross deviation from the standard of care that an ordinary person would exercise under all the circumstances.’” Brown v. Hamilton Cty., 126 S.W.3d 43, 49 (Tenn. Ct. App. 2003) (quoting Gardner v. Insura Property & Cas. Ins. Co., 956 S.W.2d 1, 3 (Tenn. Ct. App.1997)).

1. Defendants’ Claim of Comparative Fault Against the FDA

Defendants allege that the FDA acted recklessly because it was aware that NECC had sterility and potency issues with MPA as early as 2002 but failed to take any “meaningful, substantive action.” Docket # 1456, at ¶ 48(ee). Specifically, Defendants allege that on December 4, 2006, the FDA issued a warning letter to NECC “detailing

numerous problems at NECC, including: (a) Compounding drugs without patient-specific prescriptions; (b) Compounding copies of commercially-available drugs; (c) Selling misbranded compounded drugs; and (d) Failing to correct problems with storage and sterility.” Id. at ¶ 49. Nevertheless, Defendants assert, the FDA failed to take any action against NECC after issuing this letter and, thus, proximately caused the alleged injuries.

The PSC does not contest the facts alleged by Defendants in their Answer to the Amended Complaint. See Docket # 1456. Instead, they argue that, as a matter of law, “Defendants’ repeated characterization of the FDA’s conduct as ‘reckless’ . . . do not establish **recklessness** by the FDA under the applicable legal standard.” Docket # 3288, at 8-9. They further characterize Defendants’ argument as attacking the governmental entities’ decisions on how “limited community resources should have been allocated to protect individual members of the public.” Docket # 3288, at 9.

Viewing the allegations in the light most favorable to the non-moving party, however, Defendants’ Answer contains sufficient assertions to state an affirmative defense of comparative fault against the FDA under the special duty exception to the public duty doctrine. Defendants do not generally plead that the FDA should have allocated more resources to the members of the public. Nor do they merely characterize the FDA’s conduct as reckless. Rather, they specifically plead that the FDA received numerous complaints that NECC was violating the FDA’s Compliance Policy Guidance on Pharmacy Compounding, but the FDA nevertheless failed to take any subsequent action to address the serious nature of these complaints, which proximately caused the alleged injuries. See Ford v. New Greater Hyde Park

Missionary Baptist Church of Memphis, No. W2006-02614-COA-R9-CV, 2007 WL 4355490, at *8 (Tenn. Ct. App. Dec. 12, 2007) (finding that the city was not immune from liability under the public duty doctrine when plaintiffs sufficiently alleged conduct by city official that could be deemed reckless because the city “took no protective action on a building that had been identified as possibly having serious structural problems”). At this pleadings stage, the uncontested facts do not “conclusively establish [the PSC’s] entitlement to a favorable judgment.” Aponte-Torres, 445 F.3d at 54.

2. Defendants’ Claim of Comparative Fault Against the Massachusetts Board of Registration in Pharmacy

Defendants similarly argue that the public duty doctrine does not shield the MBOP from comparative fault because it, too, acted recklessly. In response, the PSC raises the same arguments as above regarding the FDA. But, here again, Defendants’ Answer contains sufficient assertions to state an affirmative defense of comparative fault against the MBOP. Specifically, Defendants assert that the MBOP was “aware of NECC’s failure to comply with applicable state and federal laws and manufacturing guidelines,” Docket # 1456, ¶ 66, but nevertheless “failed to notify [Defendants] and other state pharmacy boards of the potential threat to public health caused by NECC’s non-public track record of regulatory non-compliance with state and federal law, and unsatisfactory results from [MBOP’s] on-site surveys.” Id. at ¶ 59. As a consequence of this alleged breach of duty, Defendants argue, that the MBOP “proximately caus[ed] all injuries and damages alleged.”⁴ Id. at ¶ 57. Thus, the properly considered facts do

⁴ Defendants also cite to November 2012 testimony by the interim commissioner of the Massachusetts Department of Public Health, Dr. Lauren Smith, in further support of their allegations that the MBOP acted recklessly. Dr. Smith testified that “[t]he Board of Pharmacy’s failure to take decisive disciplinary action in 2006 on these complaints has contributed to these tragic events.” Docket # 3278-1,

not “conclusively establish [the PSC’s] point.” R.G. Fin. Corp., 446 F.3d at 182.

3. Defendants’ Claim of Comparative Fault Against the Tennessee Governmental Entities

Since Defendants do not plead that the Tennessee Board of Pharmacy and the Tennessee Department of Health acted recklessly, they cannot, as a matter of law, establish an exception to the public duty doctrine. Ezell, 902 S.W.2d at 397. As a result, Defendants cannot assert a comparative fault defense against these entities. Biscan, 160 S.W.3d at 474–75.

III. Conclusion

The Plaintiffs’ Steering Committee’s Motion for Judgment on the Pleadings regarding Comparative Fault Defenses Attributing Fault to Governmental Entities (Docket # 3249) is ALLOWED as to Defendants’ claims against the Tennessee Board of Pharmacy and the Tennessee Department of Health, but DENIED as to Defendants’ claim against the Food and Drug Administration and the Massachusetts Board of Registration in Pharmacy.

April 24, 2017

DATE

/s/Rya W. Zobel

RYA W. ZOBEL
SENIOR UNITED STATES DISTRICT JUDGE

at 3. See R.G. Fin. Corp., 446 F.3d at 182 (“The court may supplement the facts contained in the pleadings by considering . . . facts susceptible to judicial notice.”); see also United States ex rel. Winkelman v. CVS Caremark Corp., 827 F.3d 201, 207–08 (1st Cir. 2016) (upholding district court taking judicial notice of congressional testimony). In any event, I do not rely on the facts asserted in the congressional testimony because Defendants’ Answer sufficiently pleads a claim of reckless misconduct.